SECTION 2

PHARMACY MANUAL

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1 GENERAL POLICY

The Utah Department of Health, Division of Health Care Financing (DHCF) covers most medications prescribed by qualified practitioners as a Medicaid benefit, in compliance with Federal law (42 CFR 440.120). All drugs or products must have an NDC number. [Social Security Act, Section 1927 (K)(3)] Medicaid covers legend drugs with some exceptions and restrictions outlined in Omnibus Budget Reconciliation Act (OBRA) 1990 and 1993 and further identified in this manual, some over-the-counter products, and generic products. This manual is updated by Medicaid Information Bulletins (MIBs) mailed to Medicaid providers. (The Amber Sheet, a publication of the Drug Utilization Review (DUR) Board, is not an official Medicaid publication; it contains general information and educational items.)

1 - 1 Legal References

Utah Public Law HB 231 allows pharmacists to substitute a generically equivalent drug for a prescribed name brand product. The Division of Health Care Financing requests all pharmacies to dispense generically within the intent and guidelines listed in this law and under the conditions established.

Pharmacy Practice Act: Senate Bill 79 enacted by the Utah legislature in 1996 made changes in pharmacy practice and the functions of technicians.

Controlled Substance Amendment: Senate Bill 281 adds penalties and other items to the Controlled Substances Act.

1 - 2 Federal Upper Limit List

The federal Health Care Financing Administration (HCFA)through the Federal Upper Limit Bureau provides a biyearly list to the State Medicaid agency which contains the mandated generic, multi-source level of reimbursement for the identified drugs. The Federal Upper Limit List is generally reissued January 1 and July 1. First Data Bank, under contract to Utah Medicaid, maintains these pricing regulations on the Utah Master Reference File. Generic substitution may only be made with products with an A B rating identified in the Approved Drug Products (orange book) published by the U. S. Department of Health and Human Services. The Federal Upper Limit information is available through the Medicaid Point of Sale system and on the Internet at

http://cms.hhs.gov/medicaid/drugs/drug10.asp

A printed copy of the list may be obtained by contacting Medicaid Information.

The reimbursement allowed by HCFA is determined by 150% of the average of the lowest three products in the multi-source class. The purchase of all generic products from a single manufacturer may leave some products unavailable at the FUL level. Although a pharmacy may choose not to stock multiple brands and has only products more costly than the FUL, a Medicaid client may NOT be charged the difference between the FUL and the pharmacy cost.

A pharmacy may not dispense a house brand generic product and bill Medicaid for an NDC of a name brand or generic brand product. The name or manufacturer or NDC for the product dispensed must be recorded on the prescription.

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1 - 3 Utah MAC List

The Division of Health Care Financing (DHCF), Bureau of Coverage and Reimbursement, maintains the Utah Maximum Allowable Cost (MAC).

1 - 4 New Products

Any new legend drug product, new size of an existing approved product, or new strength of an existing approved product may be reimbursable, subject to Medicaid limitations and/or prior approval. New drugs will be reviewed for limitations such as prior approval, quantity, and frequency. New drugs may be withheld from coverage for no more than twelve weeks while restrictions or limitations are being evaluated.

New drugs may also be reviewed for off-label or experimental uses. Refer to Chapter 2 - 5, Formulary.

1 - 5 Clients Enrolled in a Managed Care Plan

*A Medicaid recipient enrolled in a managed health care plan, such as a health maintenance organization (HMO), which includes pharmacy services must receive all pharmacy services through that plan. An HMO may designate a particular provider as the ONLY provider approved by the HMO to receive payment for services to an enrolled Medicaid recipient.

A provider must be affiliated with the client's managed care plan in order to receive payment for services. Each plan may offer different benefits and restrictions than the Medicaid scope of benefits. The plans which include pharmacy services specify which are covered, which require prior authorization, the process to request authorization and the conditions for authorization. All questions concerning services covered by or payment from a managed care plan must be directed to the appropriate plan.

Reference: Utah Medicaid Provider Manual, SECTION 1, GENERAL INFORMATION: Chapter 4, Managed Care Plans; Chapter 5, Verifying Eligibility - how to verify a patient's Medicaid eligibility and possible enrollment in a managed care plan.

***NOTE:** Since November 1997, none of the Medicaid HMO's have covered pharmacy services. All pharmacy services are fee-for service.

1 - 6 Fee-for-Service Clients

A **fee-for-service** client is a Medicaid client who is either (1) **not** enrolled in a managed care plan or (2) *is enrolled in a managed care plan in which pharmacy benefits are not included ('carved out'). Fee-for-service clients, with the exception of clients in the Restricted Program, may receive pharmacy services from any pharmacy provider who accepts Medicaid.

You should **REQUIRE** the client's proof of eligibility **BEFORE** you provide service and **EACH TIME** you provide service. Proofs of Medicaid eligibility are the Medicaid Identification Card or Interim Verification of Medicaid Eligibility. Proof of eligibility for the Baby Your Baby Program is the Baby Your Baby Card. Look *carefully* at the dates of eligibility on the client's card. If the card is hand-written, you may wish to copy the card to substantiate your Medicaid claim. Medicaid does not pay claims for services after the client's eligibility expires.

The Medicaid Point of Sale system 'captures' a claim even when the computer system has no information as to the client's eligibility. The system returns the message 'claim captured' to advise the pharmacy the claim has been received by Medicaid. The message 'claim captured' does NOT guarantee payment. If the system is subsequently updated, and the claim is within the client's dates of eligibility, it may be paid. If eligibility information is not posted to the Point of Sale system, the claim will be denied. You will NOT receive payment for the services given to the client unless you have a copy of the proof of eligibility the client presented at the time of service which verifies eligibility on the date of service.

Reference: SECTION 1, GENERAL INFORMATION: Chapter 3 - 2, Restricted Program; Chapter 5, Verifying Eligibility - how to verify a patient's eligibility and possible enrollment in a managed care plan.

Client Identification Numbers Ending in 'V' or 'X'

Clients whose number ends in 'V' have a Baby Your Baby Identification Card. Clients whose number ends in 'X' have an Interim Verification of Eligibility (Form 695). You may wish to copy the card or form to substantiate your Medicaid claim. When a temporary proof of eligibility expires, Medicaid will no longer pay claims, unless the client has since been issued a Medicaid Identification Card for the month of service.

Expiration Date on Baby Your Baby Card

A woman eligible for a Baby Your Baby Card is told to present the Card **each time** she requests prenatal services. The card has an **initial expiration date** pending a formal decision of eligibility for Medicaid. If a determination of Medicaid eligibility cannot be made before the initial card expires, the **Medicaid eligibility worker may extend** the expiration date on the card.

Expiration Date on Interim Verification of Medical Eligibility (Form 695)

An "Interim Verification of Medical Eligibility" (Form 695) with date limits may be issued by the Medicaid eligibility worker when a client needs proof of eligibility and does not yet have the Medicaid Card.

1 - 7 Retrospective Drug Utilization Review (RetroDUR)

The State Drug Utilization Review Board will use Retrospective Drug Utilization Review (RetroDUR) studies to review prescribing and dispensing patterns for Medicaid patients. The Board is comprised of providers nominated by the Utah Medical Association, the Utah Pharmaceutical Association, and the Utah Dental Association.

RetroDUR studies are required by the Omnibus Reconciliation Act (OBRA) of 1990. The University of Utah College of Pharmacy developed the drug criteria sets. Academicians from the School of Medicine and the School of Pharmacy reviewed the sets with the Drug Utilization Review (DUR) Board. Sets approved by the DUR include:

- Antidepressant drugs
- Centrally acting skeletal muscle relaxants
- Gastrointestinal agents
- Nonsteroidal anti-inflammatory agents
- Migraine usage
- Oral asthma / inhalation
- Oral opioids
- Antidepressants
- Lipodemics
- Atypical Antipsychotics

To order a copy of the drug criteria sets, please contact Medicaid Information.

1 - 8 Copayment Required for Medicaid Prescriptions

Effective July 1, 1997, most Medicaid recipients are required to pay a $3.00 copayment for each prescription filled. **The Point of Sale system informs you when a copayment is due.** When Point of Sale (POS) shows a $3.00 copayment, the Medicaid recipient is expected to pay the $3 in order to receive the prescription. There is a $15.00 monthly maximum on copayment in the Traditional Medicaid Program.

1. Recipient Notification

Medicaid recipients who are required to pay the copayment receive a Medicaid Card which states 'Copayment required for pharmacy'. The July 1997 Medicaid Cards were the first ones with this message. A letter was sent with both the June and July 1997 Medicaid Cards to inform recipients of the new requirement.

2. Exempt Recipients

Some Medicaid recipients are exempt from the pharmacy co-payment, due to age or other specific criteria. Point of Sale will not indicate a copayment when the recipient is exempt.

A. When any or all of the recipients listed on the Medicaid Card are required to pay the copayment, the Card will have the 'Copayment required' message. Because a family eligible for Medicaid may contain adults required to make a copayment and children who are exempt from the requirement, **you must use Point of Sale** to know whether the patient with a prescription has a copayment or not.

B. When all of the recipients listed on the Medicaid Card are exempt, the Card will NOT have the message 'Copayment required for pharmacy'.

For your information, the following groups of Medicaid recipients are exempt from the copayment requirement:

(1) Recipients enrolled in an HMO that includes prescription drug coverage, with one exception for protease inhibitors as described in paragraph number 5. NOTE: As of November 1997, none of the Medicaid HMO's cover pharmacy services. All pharmacy services are fee-for service.

(2) Children under age 18.

(3) Residents of a nursing home who are entitled to keep only the $45 personal needs allowance.

(4) Pregnant women, as determined by the Medicaid eligibility worker.

(5) Recipients whose monthly household income is less than the payment amount in the Family Employment Program, as determined by the Medicaid eligibility worker.

3. No Copay on Prescriptions for Family Planning

Point of Sale will NOT indicate a copayment on family planning prescriptions, such as birth control pills.

4. Maximum $15.00 a month Copayment for Each Recipient In the Traditional Medicaid Plan

Once a recipient has met an individual maximum copayment of $15.00 a month for his or her prescriptions, Point of Sale will NOT indicate a copayment is due. Medicaid will keep track of the number of prescriptions for a recipient with $3.00 copayment. Once five prescriptions with $3.00 copayments have been filled, Point of Sale will no longer indicate a $3.00 copayment.

5. Protease Inhibitors

Point of Sale will indicate a copayment is due for drugs classified as protease inhibitors, even though the recipient's Medicaid Card may not have the message 'Copayment required for pharmacy'.

6. Recipients with Temporary Proof of Eligibility

When the client has an interim Form 695, Verification of Medicaid Eligibility, and the Point of Sale system (POS) does not yet display Medicaid eligibility information, we ask that you do **NOT** collect a copayment unless the form is stamped 'COPAYMENT REQUIRED.' (To ensure reimbursement when a client's number ends with letter 'X', ALWAYS require the client's proof of eligibility.) The Medicaid eligibility worker will add the statement 'COPAYMENT REQUIRED' to the top of the Form 695 when applicable for the adults listed on the form. A co-payment should **never** be collected when dispensing prescriptions for children who are under age 18.

In addition, we recommend you do **NOT** require a copayment when the prescription is for family planning, such as birth control pills.

Please note the pharmacist cannot exempt the copayment on the basis of pregnancy or household income. These exemptions can only be determined by the Medicaid eligibility worker.

Typically, POS receives eligibility information overnight. When the pharmacy claim is entered the day after the initial determination of Medicaid eligibility, the copayment indicator will state whether $3.00 will be subtracted from the reimbursement amount.

When POS displays eligibility information for the client, **you must use Point of Sale** to determine when to collect a copayment, regardless of whether the Form 695 has a copay message or not. Once a Medicaid Identification Card has been issued, POS determines when a copayment is due, even though the client may be using a Form 695 as a substitute for a missing Medicaid Card.

7. Baby Your Baby Program

NEVER collect a copayment from a client eligible for the Baby Your Baby Program on the date of service. A co-payment will **NOT** be assessed by Medicaid. When a client's number ends with letter 'V', ALWAYS require the Baby Your Baby Card and CHECK THE DATES OF ELIGIBILITY.

QUESTIONS?

When Point of Sale is not available, and you cannot determine whether a copayment is due or not, you may call Medicaid Information. In the Salt Lake City area, call 538-6155. In other areas of Utah, call toll-free 1-800-662-9651.

If a Medicaid recipient has a question about whether he or she is exempt from the copayment, the recipient should contact his or her eligibility worker. If the recipient has a question about being charged a copayment, whether for a certain type of prescription or being charged for more than five prescriptions in a month, he or she should discuss this with the pharmacist. If the recipient continues to have questions or concerns, he or she should talk to the eligibility worker.

1 - 9 Internet Access to Medicaid Manuals

SECTION 2 of this Medicaid Provider Manual is accessible on the World Wide Web. Go to the Medicaid Provider Guide web site at http://health.utah.gov/medicaid/provhtml/provider.html and choose the link to SECTION 2. The SECTION 2 list of provider manuals has links to manuals on the Internet. We suggest that, when you find the manual you want, you set a "bookmark". For example, set a bookmark for the Pharmacy Services Manual at http://health.utah.gov/medicaid/pdfs/pharmacy.pdf.

2 COVERAGE OF SERVICES

When a client wants medications not covered by the Medicaid program, the client may choose to pay for the non-covered medications. For information on the circumstances in which a client may be billed for non-covered Medicaid services, refer to the SECTION 1 of this manual, Chapter 6 - 8, Exceptions to Prohibition on Billing Patients, item 1, Non-Covered Services. The on-line version of SECTION 1 is at http://health.utah.gov/medicaid/pdfs/SECTION1.pdf.

2 - 1 *reserved*

2 - 2 Prescribed Legend Drugs

Prescribed legend drugs are covered with the following limitations:

1. Non-covered drugs which are listed in Chapter 7, Non-covered Drugs and Services.
2. Drugs which require prior approval
3. Drugs by manufacturers who have not entered into a rebate agreement with CMS.
4. Nutritional substances
5. Metabolic nutritional products

2 - 3 Prescribed Over-the-Counter Products

Over-the-Counter drugs (OTC) are covered ONLY when (1) the drug is listed on the Medicaid-approved OTC List and (2) the drug is ordered on a prescription. The OTC list is included with this manual.

OTC drugs are identified in OBRA 1990 as a category that a state may choose not to cover. Utah has chosen to include as a benefit a limited list of over-the-counter products. This list is reviewed twice a year for changes, additions, or deletions. Changes to the list are published in the Medicaid Information Bulletin.

Only the Over-the-Counter drugs on the latest list published in the Medicaid Information Bulletin (MIB) are reimbursable. No other formulas or similar products are a benefit. Because it would require extensive auditing to adjust prices to every pharmacy level of purchase and sale price, a fee of $1.00 is paid on all over-the-counter products.

1. OTC drugs NOT on the approved list are NOT covered.
2. Certain OTC drugs on the approved list are not a benefit for a Medicaid client who is a resident of a nursing home. When this restriction on a drug is indicated, all dosage forms apply.
3. Limits and criteria may also be noted on the OTC list after the drug name.
4. Excessive utilization or waste may cause the whole class to be dropped from the program.
6. OTC drugs are not covered for manufacturers who have not entered into a rebate agreement with CMS.

2 - 4 Generic Preparations

Medicaid requires use of generic drugs, unless the physician obtains a prior approval for the brand name drug. However, Medicaid does not pay for generic house-brand or store brand products unless the manufacturer has entered into a rebate agreement for each specific NDC number. Manufacturers that have not entered the federal rebate program will not have their products covered. This includes almost all 'house brand' and 'store brand' products.

2 - 5 Formulary

OBRA 1993, Section 1927 (d) (6) states: "Effective October 1, 1993, states may exclude, restrict, or subject to prior authorization new drugs approved by the Food and Drug Administration (FDA)." However, Utah law prohibits Utah Medicaid from having a closed formulary. Utah Medicaid maintains an "open" formulary with a few drug classes not covered as allowed by OBRA and Utah Law. This chapter explains Utah's formulary.

Amendments to the law have been made to allow HMO's to have Preferred drug lists.

A. Non-Covered Drugs

OBRA 1990, Section 1575 (d) (2) states: "The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted by a state participating in the master rebate agreement."

1. Agents when used for anorexia, weight loss or weight gain.
2. Agents when used to promote fertility.
3. Agents when used for cosmetic purposes or hair growth.
4. Agents when used to promote smoking cessation.
5. Prescription vitamins and mineral products except prenatal vitamins for pregnant women and fluoride preparations for children to age five. Refer to Chapter 5 - 14, Prenatal Vitamins.
6. Nonprescription drugs. However, Utah has chosen to pay for a limited list of OTC drugs.
7. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests and monitoring services are purchased exclusively from the manufacturer or its designee.

OBRA 90 also includes barbiturates, benzodiazepines, and cough and cold preparations. Utah Medicaid has chosen to include these items as covered products. Utah has also chosen to exclude coverage of drugs available only through unique, single-source distribution programs.

B. Off-Label, Experimental and Investigational Drugs

The Utah Medicaid Program restricts the covered drug products on the open formulary to uses approved and documented by the officially recognized compendia [OBRA 1993, section 1927 (d) (6)]. The designated compendia are:

1. Package insert, FDA approved uses
2. American Hospital Formulary Service Drug Information (AHFS)
3. American Medical Association Drug Evaluation (AMADE)
4. United States Pharmacopeia Drug Information Drug Information (USP- DI)
5. DRUGDEX

Off-label Use

The Drug Utilization Review (DUR) Board may approve an unlisted off-labeled use for a given drug if the off labeled use meets ALL of the following criteria.

1. Use must be diagnosis specific as defined by an ICD-9 code (s).
2. Off-labeled use must be supported by one major multi-site study or three smaller studies published in JAMA, NEJM, Lancet or peer review specialty medical journals such as Journal of Cardiology. Articles must have been published within five years.
3. Off-labeled use must have a defined dosage regimen.
4. Off-labeled use must have a defined duration of treatment.
5. The off-labeled use shows clear and significant clinical or economic advantage over existing approved drug regimens.

Experimental Use

Experimental use is defined as drug use for indications not supported by FDA or published studies. Drugs prescribed for experimental use are **not** covered. Experimental drugs or herbal products are not covered. As documentation accumulates for a given indication, the experimental drug use may move to the off-label category or be approved as a labeled indication, as determined by the DUR Board.

Investigational Use

Investigational drugs or chemicals are not covered. Any drug or chemical that does not have an NDC number is deemed investigational.

The UMA, Utah based Group Practices or Utah based prescribers have the option of petitioning the DUR Board for coverage for an unlisted, off-labeled use of a given drug. The petitioner(s) must schedule an appearance before the Board to present the case for the petitioned drug. Petitioners must provide documentation including one published major multi-cite study or a minimum of three recent (five years) articles from JAMA, NEJM, Lancet or peer review specialty medical journals such as the Journal of Cardiology, supporting the petition's position. If possible, the documentation must be submitted six weeks in advance of the scheduled DUR Meeting.

3 PRIOR APPROVAL

Prior Authorization (PA) confirms that services requested are needed and reimbursable by Medicaid, that they conform to commonly accepted medical standards, and that all less costly or more conservative alternative treatments have been considered.

Prior authorization falls into two categories.

1. Services or drugs beyond the designated limitations

2. Services or drugs specifically identified as requiring prior authorization

The pharmacist is responsible for requesting the prior authorization based on information supplied by the physician and in accordance with the requirements stated on the Drug Criteria and Limits List. If any exception is noted, Medicaid requires a pharmacist to obtain prior authorization in writing or by telephone in advance of the date of service. Products which require prior approval are on the Drug Criteria and Limits List with a description of the type of approval required and the criteria. The list may be amended by Medicaid Information Bulletins.

Prior authorization for a pharmaceutical is client specific, pharmacy specific, and product specific. Prior authorization cannot be transferred to another pharmacy, to another product, to another strength of a previously priored product, nor to another client. Refer to Chapter 3 - 2, Prior Authorization Is Provider Specific.

3 - 1 Fee-for-Service Clients

Prior authorization requirements for pharmacy services apply to ALL fee-for-service clients, defined in Chapter 1 - 6, even though the client may be enrolled in a managed care plan which provides other types of health care services.

The PA requirements and process do **not** apply to Medicaid patients enrolled in managed care plans which include pharmacy services. Those plans specify which services require authorization and the conditions for authorization.

NOTE: Medicaid staff make every effort to ensure information provided is accurate. However, obtaining a prior authorization number does not ensure that the client is eligible for Medicaid on the date of service, and neither does it ensure that the client is not enrolled in a managed care plan which includes pharmacy services.

3 - 2 Prior Authorization Is Provider Specific

When a pharmacy requests prior authorization, the prior authorization number includes the pharmacy's Medicaid Provider Identification Number. The authorization number is valid only for the pharmacy provider requesting authorization. It is not transferrable to another pharmacy provider, including another store in the same chain. For example, prior authorization given to ABC Pharmacy #00 for John Doe for growth hormone cannot be used by XYZ Pharmacy nor by ABC Pharmacy #99.

Claims submitted for drugs which require prior authorization can be paid only when the prior authorization number for the drug matches the provider number on the claim. Claims will be denied when the prior authorization number does not match the provider number. Claims submitted through the Medicaid Point of Sale payment system which deny for this error reason will state: "Claim submitted does not match prior authorization."

If the prescription is transferred to a different pharmacy, the existing prior approval (PA) must be terminated. The new pharmacy can then request its own PA for the remaining doses. The new pharmacy must obtain all information and documentation required for the PA. It may either obtain this from the pharmacy with the original PA or from the prescriber. Medicaid will assign a new PA number with the original end date for the residual doses. The second pharmacy cannot start the prescription with a new number of doses or a new time span.

3 - 3 Prior Authorization Process

1. A pharmacist may request prior approval by telephone supplying identified information specified on the Drug Criteria and Limits List, or the pharmacist may initiate and complete the Request for Prior Approval Form (PA-3) when necessary. The prescriber furnishes information to justify the need. The pharmacist submits the form. The form does not require a prescriber's signature. **Request for renewing a prior approval must contain justification in box 20, along with any additional information required. Do not refer only to the previous prior approval number.**

   a. Written Prior Authorization

      Contact Medicaid Information to obtain Prior Approval Request Forms. All data elements must be completed on this form as instructed. Mail written requests to:

      MEDICAID PRIOR AUTHORIZATION
      P.O. BOX 143103
      SALT LAKE CITY UT 84114-3103

   b. Fax Number

      Prior authorization requests may be faxed to **(1-801) 538-6382**, attention "Prior Authorizations"

c. Telephone Prior Authorization

Call Medicaid Information, then follow the telephone menu prompts.

In the Salt Lake City area, call **538-6155**

Call toll-free in Utah, Arizona, New Mexico, Nevada, Idaho, Wyoming and Colorado **1-800-662-9651**

From all other areas **1-801-538-6155**

2. If documentation is complete and the request is approved, Medicaid notifies the provider of the prior authorization number. The provider supplies the services to the recipient and bills the Department of Health, Division of Health Care Financing, through the Point of Sale adjudication system identifying the prior approval number.

3. If documentation is incomplete, the prior approval specialist outlines documents or actions necessary to approve the request for telephone or written prior approval.

4. If the prior approval request is denied, a letter of denial with an explanation is returned to the requestor, and a copy of the denial and explanation is sent to the recipient.

   Any further questioning by provider must be referred to the prior approval specialist who is responsible for the initial action. The signature on the denial or the signature on the letter of information will identify the specialist.

4 COVERAGE LIMITATIONS

Medicaid coverage of pharmaceuticals is subject to the limitations described in this chapter. When the drug requires prior approval, it is included on the drug criteria chart with any age restriction indicated.

4 - 1 Gender and Age of Patient

Drugs must be for the correct gender and/or appropriate age. Examples of gender specific drugs are as follows:

Drug type	Gender
Prenatal	Female
Oral contraceptives	Female
Estroderm	Female
Caverject	Male

Age limitations on drugs are announced in the Medicaid Information Bulletin. Examples of age restrictions are multiple vitamins, a Medicaid benefit only for children through age five; Multiple vitamin supplement (vitamins A, C, and D) without fluoride covered for children up to five years of age only; acne preparations, only for children through the month of the twenty-first birthday

4 - 2 Maintenance Drugs

Definition: A maintenance medication is any medication or covered pharmacy supply used on an ongoing basis.

Medicaid does not cover any payments for dispensing medications in excess of the practitioner's order. If special circumstances warrant, the pharmacist must provide written documentation on the prescription which must be available for review by the Division of Health Care Financing.

The pharmacist will receive payment for maintenance medications on the basis of one and only one professional fee for:

1. each 30 or 31 days supply of tablets, capsules, bulk liquids, or topicals: or

2. manufacturers' prepackaged powders, topicals, ophthalmic, optics, nasal preparations, and liquids not available in bulk.

3. a trial quantity of less than 30 or 31 days' supply;

4. glucose test strips. Refer to Chapter 5, Special Drug Provisions, item G.

4 - 3 Controlled Substances

Controlled drugs in Schedule II, which are highly regulated and specifically and totally controlled, must be dispensed as written, and will be reimbursed on that basis for all Medicaid clients.

Schedule medications (C - III, IV, or V) are not classified as maintenance medications for reimbursement purposes although they may otherwise fulfill maintenance medication criteria. Physicians may prescribe a 30 day supply.

4 - 4 Brand Name Drugs and Override

Brand name drugs require a prior approval if an 'AB' rated generic alternative is available. The Utah Pharmacy Practice Act mandates use of a generic unless the treating physician demonstrates to the Department of Health a medical necessity for dispensing the non-generic, brand-name legend drug. Prior approval can be obtained by FAXing a copy from the patient's medical record that documents that the patient has had an unacceptable adverse drug reaction to the generic version that does not occur with the name brand or has failed to achieve therapeutic efficacy with the generic version. [42 Code of Federal Regulations § 447.331© and § 447.331(c)(3)]. If the prescription does not meet coverage requirements, brand name reimbursement is not covered, and Medicaid will retract the entire payment. Telephone orders are not acceptable for brand name drugs unless the pharmacist has received the FAXed documentation ruling out use of a generic. The pharmacist can then forward that FAX to the Medicaid prior approval unit. Pharmacist will still have to activate the DAW override loop to get full reimbursement on a brand name one a prior approval has been obtained.

Patient preference does not constitute a medical necessity.
Example: There is both a name brand and a generic available based on the client's prescription for 90 tablets. The name brand costs $0.22; total cost of product is $19.80. The generic brand costs $0.04; total cost of product is $3.60. The client may choose the generic brand covered in full by Medicaid or choose to pay the difference between the cost of the two products. In this example, the difference in cost is $16.20.

If the brand name is not covered, and the client chooses the brand name drug, the client is responsible for the entire payment. For example, Valium® is not covered by Medicaid because the manufacturer does not participate in the rebate program. If the prescription is for Valium®, and the client chooses Valium over the generic product, the client must pay the entire cost.

4 - 5 Drugs for Nursing Home Patients

With the exception of Schedule II drugs, all medications should be dispensed to nursing home clients with a 30 or
* 31 days' supply.

1. Take Home Drugs

   Medicaid reimburses the pharmacy for a 30 or 31 days' supply of drugs for nursing home patients. If a patient is leaving the facility for therapeutic or social reasons, the dispensing pharmacist must provide a labeled take-home container and must place in the container the specific number of units required for the patient while away from the nursing home. These units are to be taken from the month's supply already provided. No additional units beyond the 30 or 31 days' supply will be reimbursed.

2. Cycle Filled Prescriptions

   Cycle filling of prescriptions is NOT acceptable to Utah Medicaid. A prescription may not be refilled until a minimum of 80 percent of the previous prescription has been used. Refer to Chapter 4 - 7, Early Refills.

   The term "cycle" means some action or procedure performed on a routine basis. For example, 'cycle filled' prescriptions are those filled on a set schedule, usually every 30 or 31 days, with no reference to the use of the previously dispensed prescription. Typically, the routine is to dispense a month's supply of medication for the patient under the physician's orders. At the end of the "cycle," the local or mail order pharmacy delivers to the nursing home or patient's home a new 30 or 31 days' supply of all prescriptions without adjustment for unused units.

   Prescriptions furnished to patients residing in extended care facilities (nursing home) MAY NOT be refilled until the previous prescriptions are used, even when an extended period of time occurs. For example, Darvocet is dispensed generically in a quantity of 60, to be taken two daily. If the patient does not actually take the medication as indicated for 45 or 50 days, the prescription may NOT be reordered or refilled.

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   Unique dispensing methods such as tray changes every two days or every seven days do not justify additional fees. One fee per month is reimbursable even when the product is delivered to a nursing home one tablet at a time.

3. Drug Recycling Program

   Nursing Homes and other LTCF will perform a monthly accumulation and inventory of patient medications that have been discontinued and/or left behind by clients. These medications must be returned to the pharmacy which in turn will credit their value to the Division. Logs of returned drugs must be maintained by both the LTCF and the pharmacy. The Division will provide the forms for the log book. Scheduled drugs and opened vials, tubes, etc. are not to be recycled.

4 - 6 Compounded Prescriptions

Compounded prescriptions are usually an arrangement between a physician and a specific pharmacy to provide a privately designated combination of drugs as a specific entity. Pharmacists sometimes call compounded prescriptions 'simple dilutions' or simple combinations of two already available ointments. These physician and pharmacy arrangements are not in question.

However, effective February 1, 1997, **each ingredient covered by Medicaid must be billed with its own prescription number and the appropriate quantity**, from one tablet to multiple grams of ointment. In other words, a separate claim must be submitted for each covered product used to formulate the compounded prescription which has an NDC number and is covered by Medicaid. Include your usual dispensing fee with each claim submitted. (Usual fees are $3.90 for pharmacies in urban areas, $4.40 for pharmacies in rural areas, and $1.00 for an over the counter product.) Multiple ingredients will receive multiple fees, while single ingredient compounds with noncovered diluents or bases will receive one fee despite the difficulty of some compounded entities.

Medicaid will reimburse for the covered drugs dispensed, **plus a single dispensing fee per claim paid**. If a single ingredient in a compounded prescription is billed, a single fee is paid. If two claims (for two ingredients with NDC's) are billed, two fees are paid. . . and so forth. The form in which the ingredients are dispersed (capsule, liquid, suppository, cream, etc.) does not affect reimbursement.

Following are three examples of reimbursement under the compounded policy:

1. A compounded prescription calls for 10 tablets (with an NDC number) to be crushed and placed in a liquid which does NOT have an NDC number. Submit a single claim for the tablets with the NDC number, plus your usual fee. Do not bill for the non-covered liquid. Medicaid will reimburse for the tablets and one dispensing fee.
2. A compounded prescription calls for 10 tablets (with an NDC number) to be combined in a liquid which also has an NDC number. Submit two claims, each with a different prescription number. One claim will be for the tablets with the NDC number, plus your usual fee. The second claim will be for the liquid, plus your usual fee. Medicaid will reimburse for the tablets and for the liquid, plus two dispensing fees.
3. The prescription to the right illustrates a compounded prescription. The pharmacist should submit two claims. Bill Decadron, 60 ml, and the usual fee of $3.90. Using a different prescription number, bill Benadryl Elix, 60 ml, and the usual fee, either $3.90 or $1.00. Simple syrup is not covered by Medicaid, so do not submit a third claim. Medicaid will reimburse for the two legend drugs, plus a total dispensing fee of either $7.80 or $4.90, depending on the fee submitted for the Benadryl Elix.

Jane Doe 10 State Street	June 9, 1994
Decadron	60 cc
Benadryl Elix	60 cc
Simple syrup	60 cc
Sig: 1 teaspoonful q.i.d.	Signature: J.Doe, M.D.

Claim Form Instructions

When filing a claim electronically through the Point of Sale System, leave field 406 - *Compound Code* blank. When filing a paper claim, do NOT enter "Compound X" under the field labeled 'National Drug Code'.

4 - 7 Early Refills

Medicaid provides up to a 30 or 31 days' supply of a medication to Medicaid clients each month. Once that has been done, the Division's responsibility has ended. Medicaid pays for a prescription refill ONLY WHEN 80% of the drug is used in accordance with the physician's orders on the prescription and on the label of the medication. For example, a prescription for a 30 or 31 days' supply has been 80% used by the 24th day after it was dispensed and it may be refilled at that time.

A. Early Refills Not Authorized

Medicaid will not pay for a prescription refill under any of the circumstances listed below. Any attempt to refill a prescription through the Point-of-Sale system under these circumstances will be automatically denied.

1. 80% of the drug, in accordance with the physician's orders on the prescription and on the label of the medication, has not been used. For example, a prescription for a 30 or 31 days' supply has not been 80% used until the 24th day after it was dispensed.

2. Medicaid will not pay for a prescription refill when the client does not like the generic version of the prescription, even though the physician writes a new prescription for the name brand. The client may choose to pay for the name brand units or use the generic until the 80% usage or the 24th day is exhausted.

3. Medicaid will not pay for a prescription refill because the client will be out of town for an extended period of time (so-called 'vacation refill.')

4. Medicaid will not authorize an early refill for medications used for palliative treatment or when gross negligence has been displayed by the client.

5. Medicaid will not authorize an early refill for drugs limited by quantity for any 30-day period. Refer to Chapter 4 - 9, Limits on Certain Drugs, and to the Drug Criteria and Limits list included with this manual.

B. Early Refill Edit Override Discontinued

The Early Refill Edit Override was discontinued October 1, 2001. For an explanation, refer to Medicaid Information Bulletin titled "Pharmacy Claims: Electronic Override for Early Refills Discontinued", published October 2001. [http://health.utah.gov/medicaid/pdfs/october2001.pdf]

4 - 8 Replacement

Medicaid does not pay for replacement of prescriptions which are lost, stolen or otherwise destroyed. Replacement of prescriptions is the client's responsibility. The early refill policy described in Chapter 4 - 7, Early Refills, does not allow replacement, even though the physician may write a second prescription to cover the loss. A request may be made to allow the early refill, but only in cases of lifesaving necessity.

4 - 9 Limits on Certain Drugs

Drugs identified on the Drug Criteria and Limits List included with this manual are limited by quantity for any 30-day period. These drugs have a cumulative limit and do not qualify for early refills under Chapter 4 - 7, Early Refills. The limits are those approved by the Drug Utilization Review (DUR) Board. Physicians and other prescribers who feel that a patient has specific needs which exceed the limits may appeal to the DUR Board. All medications remain subject to all other requirements of the Utah Medicaid Pharmacy Program, as described in the Utah Medicaid Provider Manual for Pharmacy Services.

4 - 10 Restriction on Package Size or Description

Medicaid reserves the right to restrict coverage on certain package sizes or package descriptions. For example, Medicaid may choose to pay for a drug in a MDV (multidose vial) and deny coverage of the same drug packaged in ampules.

4 - 11 Multiple Dispensing Fees Associated with Home Infusion Pharmacy Services

The U.S. Department of Justice (DOJ), as part of a legal process, established a "true AWP" for 437 NDC specific products in 2001. The "true AWP" is close to actual acquisition costs. As a result of the directive from the U.S. Department of Justice (DOJ), effective August 1, 2001, the Division of Health Care Financing has established multiple dispensing fees associated with select home infusion pharmacy services. To implement this change in dispensing fees, the Division established an Infusion Committee with representatives of the home I.V. infusion specialty pharmacies. The group placed each of the 437 NDCs in one of five categories, according to difficulty of preparation and overhead costs.

Categories range from one through five. Category one is for services deemed to be the same as those prescriptions normally filled at a typical retail pharmacy. Category five is the most difficult and expensive to prepare.

- Category two includes nebulizer preparations, growth hormone, etc.
- Category three includes simple I.V. antibiotics, anticoagulant treatments, I.V. gamma globulin, etc.
- Category four includes complex antibiotics that require laboratory monitoring and reporting.
- Category five includes chemotherapy I.V.s, pain management, and cardiac ionotropics. For example, chemotherapy requires a separate vertical hood and complete gowning to meet OSHA standards, which adds considerable expense of time and set-up costs.

Categories two through five will have a new dispensing fee effective August 1, 2001.

Category 2	$ 8.90
Category 3	$ 18.90
Category 4	$ 22.90
Category 5	$ 33.90

The 437 NDCs identified by the DOJ will be linked to their counterparts for other manufacturers. Other brands will be reimbursed at the same rate as the DOJ's 437 NDCs. All pharmacies will be reimbursed at the same rate for these NDCs.

5 SPECIAL DRUG PROVISIONS

This section contains information for pharmacies concerning particular drugs or drug classes.

5 - 1 HIV/AIDS Drugs (Protease Inhibitors)

Antiviral therapy, viral blood testing and protease inhibitor provisions are accepted Medicaid treatment for HIV/AIDS patients. All retro viral drugs are reimbursable and protease inhibitors, available in the marketplace through regular channels, are also reimbursable. No prior approval is required.

*

5 - 2 Drugs for Schizophrenia

Clozaril now has generic versions on the market. Newly diagnosed patients are expected to be placed on generic clozapine. Providers are expected to convert all patients to clozapine unless the patient has a history of repeated decompensations.

5 - 3 H Pylori Treatments

Many ulcers are due to infection with the Helicobacter pylori organism. This infection may be eradicated with a short term treatment composed of Metronidazole, tetracycline hydrochloride and bismith subsalicylate. Other combinations with different antibacterials such as Biaxin are also used. New combinations are appearing daily. The treatment is Medicaid approved, but continued use of anti-ulcer medication after the treatment regimen is completed is usually unnecessary.

5 - 4 DESI Drugs

DESI drugs are combinations of products and single products that, in the Federal Drug Efficacy Study Information (DESI), have not been proven to the federal Health Care Financing Administration (HCFA)to be effective for the conditions indicated on the label or in the information packet. DESI drugs are not reimbursable.

DESI drugs are classified by HCFA and the manufacturers of combination products into five groups numerically identified beginning with Group 2. The groups are:

Group 2 Drugs for which Medicaid will receive federal matching funds for the drug program and the indications for product use have been proven effective.

Group 3 Drugs classified as largely effective for indicated uses and for which federal matching funds are available.

Group 4 Drugs classified as possibly effective for indicated uses and for which federal matching funds are occasionally (perhaps) available.

Group 5 Drugs classified as not effective for indicated uses and for which federal matching funds are not available.

Group 6 New drugs not classified and for which federal matching funds are not available.

Utah Medicaid reimburses drugs in Groups 2 and 3 only. The DESI classification for each product is on the Point of sale System. Drugs in groups 4, 5, and 6 are considered DESI drugs and are NOT covered by Medicaid. A list of DESI drugs is available from the Medicaid Pharmacy Unit.

5 - 5 Enteral and Parenteral Nutrition and Food Supplements

Enteral nutrition is provided to Medicaid patients by a nasogastric, jejunostomy or gastrostomy tube into the stomach or intestines to supply total nutrition when a non-functioning part of the gastro intestinal tract is present.

Parenteral nutrition is total nutrition administered by intravenous, subcutaneous, or mucosal infusion.

Enteral and parenteral nutrition are reimbursable to pharmacies ONLY through the medical supplies program using five digit codes and billing in the HCFA 1500 format, electronically or on a paper claim. Refer to the Utah Medicaid Provider Manual for Medical Suppliers.

Some nutrients may have an NDC and remain non-reimbursable in the Pharmacy Program.

Clients requiring total nutrition through surgically attached tubes or semi-permanent nasogastric tubes may have liquid nutritional products that are reimbursable through the Medical Supplies Program.

5 - 6 Anti-Ulcer Drugs

Over-the-counter (OTC) forms of anti-ulcer drugs are covered. These can be written on any prescription pad or phoned in. The Medicaid Anti-Ulcer Drug Prescription Form is not required. The physician must write for the largest package sizes, either stating the amount or simply writing "largest package size" on the prescription. Below is a list of products and acceptable package size. No other units of OTC anti-ulcer drugs will be accepted.

H_2	package size
Axid AR	30
Pepcid AC	50 and 80
Tagamet HB	30
Zantac-75	20

5 - 7 Glucose Monitors with Test Strips

Glucose monitors are available to Medicaid clients with no charge to Medicaid. The Monitor Accu-Check® is provided from the manufacturer to Medicaid clients at no charge. The pharmacists must work with the manufacturer for replacement or reimbursement of monitors. Medicaid need not be contacted

The Accu-Check test strips and all other test strips are Medicaid benefits for the number of tests identified by the physician. Medicaid reimburses pharmacists AWP plus fee - no percentage deduction.

5 - 8 I. V. Therapy

The purpose of I.V. therapy is to sustain life, reduce or eliminate infections, replace or provide necessary chemicals to maintain electrolyte balance, and provide blood products or chemotherapeutics. I.V. therapy and treatment are only used when the Medicaid client cannot use oral medications. I.V. drugs are available through the Pharmacy Program. Supplies are billed through the Medical Supplies Program. Home health nursing is available through the Home Health Program.

Care must be taken when requesting reimbursement for I.V. products. Liquid injectables (before and excluding diluents) are billed as milliliters. Dry powder, by lyophilized vials, are billed as "each," or a unit of one. Diluents covered by Medicaid are billed separately by NDC and quantity such as 50 ml., 100 ml., 1000 ml.

5 - 9 Niche Drugs

Products mailed directly to a patient from the manufacturer using a single designated distributor are not covered by Medicaid. Manufacturers are increasingly shipping products, developed to target specific diseases, directly to patients via a Pharmacy Benefit Management service.

Medicaid will not enter into agreements or utilize distribution programs that violate patient confidentially or prohibit free trade of a product. When products are available through usual and customary channels to all pharmacies, the products will become Medicaid benefits.

5 - 10 Growth Hormones

Only the labeled indications of growth hormones (somatrem, Protropin; somatropin, Humatrope, Nutropin) are a Medicaid benefit for children eighteen years of age or younger. Growth hormones require prior authorization. Refer to the Drug Criteria and Limits List included with this manual for conditions of coverage. Growth hormones are not covered for adults age nineteen and older. Reimbursement for growth hormones is limited to:

1. Long term treatment of children who have growth failure due to a documented lack of adequate endogenous growth hormone secretion.

2. Somatropin (nutropin only). Treatment of children who have growth failure associated with documented chronic renal insufficiency up to the time of renal transplantation. Somatropin is a Medicaid benefit only when used in conjunction with optimal management of chronic renal insufficiency.

3. Growth hormones may be covered, by special criteria, for AIDS wasting syndrom through a prior approval process

5 - 11 Prograf

All **oral** dosage forms of tacrolimus (Prograf) are a covered benefit for use as a prophylaxis of organ rejection in allogeneic liver transplants only. All injectable dosage forms are covered in physician office or hospital only.

5 - 12 Amphetamines

The criteria below must be met to justify the use of amphetamines for ages 19 and older for a diagnosis of Attention Deficit Disorder (ADD). These criteria are on the Drug Criteria and Limits List which is included with this manual.

* A. The pharmacy is responsible for collecting and forwarding the information listed in this bulletin with the written request for prior authorization.

   1. The Wender Utah Rating Scale is documented to be at least 46, as specified in Ward, M.F., Wender, P.H., and Reimherr, F.W., the Wender Utah Rating Scale, American Journal of Psychiatry, June 1993; 150 (6): 850-90, which is adopted and incorporated by reference.
   2. Documentation that the DSM-IV diagnostic criteria for ADD, which is adopted and incorporated by reference, was met when the patient was a child.
   3. Identify the ICD-9 code used for diagnosis of the patient for adult ADD.
   4. Include a copy of the patient's medical records that support the physician's diagnosis of ADD.
   5. Include information about the patient's past and present drug use for the treatment of ADD or psychiatric disorders.
   6. Include any history of substance abuse (such as narcotic) and current status of abuse.

B. A maximum of six month's prior approval may be granted. Extension or renewal requires proof of improvement with data/documentation supplied by the provider and physicians.

C. Any of the following disorders precludes payment of amphetamine for adult ADD:
   1. Antisocial Personality Disorder
   2. Schizophrenia
   3. Schizo Affective Disorder
   4. Schizo Typical Personality Disorder or Traits
   5. Borderline Personality Disorder or Traits
   6. Active Substance Abuse or Dependance

5 - 13 Blood Factors

Medicaid restricts hemophilia blood factors to a single provider. The purpose is to provide a uniform hemophilia case management support program to the patient and patient's physician and to achieve economies in the purchase of blood factor through a sole source contract. Medicaid will reimburse only the sole source provider for hemophilia case management, blood factors VII, VIII and IX. No other provider will be paid for blood factors VII, VIII or IX. Medicaid clients who choose not to participate in the Medicaid Hemophilia program must make their own arrangements for procurement and payment of the blood factor.

The contract affects only the procurement and management of the prescribed blood factor. The patient's physician continues to be responsible to develop a plan of care and to prescribe the blood factor. The contract with the sole source provider specifies the provider must work closely with the patient's Primary Care Provider physician or managed care plan.

Managed care plans which contract with Medicaid continue to be responsible for hemophilia-related services such as physical therapy, lab work, unrelated nursing care, and physician services.

As of October 2000, the sole source provider is University Hospital Home Infusion Services. Please direct questions concerning hemophilia case management and blood factors VII, VIII and IX to this provider: 801 - 466-7016.

5 - 14 Prenatal Vitamins

Prenatal vitamins are covered only for pregnant women. Prenatal vitamins are not covered post-delivery. As part of the counseling requirement, establish the client's due date (month and year) and write it on the prescription. The due date notation will suffice for audit purposes.

All prenatal vitamins are reimbursed with a Utah MAC.

5 - 15 Schedule-2 Narcotic Analgesics

The DUR Board has restricted select schedule-2 narcotic analgesics effective 10/1/03. Those restrictions are:

Actiq® (fentanyl citrate) lozenge will be covered only for diagnoses of malignant neoplasms, carcinoma in situ, or neoplasms of unspecified nature. An absolute cumulative limit of 120 units per any 30 days is maximum amount covered. Prescribers must write the appropriate ICD.9 Code (first four digits) on the prescription.

For chronic non-malignant pain, the following long acting formulations are restricted to a maximum daily dose of: morphine sulfate SR 150mg or 90 capsules/tablets per any 30 day period; Duragesic® up to and including 75mcg - 15 patches per any 30 day period; OxyContin® up to 100mg daily or 90 tablets in any combination per any 30 day period. Methadone 50mg per day. Physicians may petition the DUR Board for a patient specific override exceeding theses guidelines.

For clients with severe progressive malignant neoplasms, carcinoma in situ, or neoplasms of unspecified nature, end stage AIDS, or Pagent's Disease an override may be gained by the physician simply by writing in an appropriate 4 digit ICD.9 code. The pharmacist must enter that code into the diagnoses field when processing each claim.
No therapeutic duplication (different chemical) is allowed for the long acting narcotics.

5 - 16 NSAIDS/Cox-2 agents

The DUR Board has placed the COX-2 inhibitors on prior approval for all clients under the age of 65. Clients age 65 or over do not require prior approval for COX-2 inhibitors.

Those clients under age sixty five may have a ten day supply for pain management. The pharmacy gets this PA.

In order for the client to have obtain a COX-2 agent for use as an anti-inflammatory agent, the client must have a secondary documented diagnosis or condition of:

GERD
Barrett's Syndrome
peptic ulcer
gastro hypersecretory conditions
documented gastric bleeding caused by other NSAIDS
documented history of bleeding ulcers
concomitant anticoagulant therapy
concomitant oral corticosteroid therapy

The physician must provide the documentation to get the PA for inflammatory conditions.
Dosing amounts are limited to package insert.

Celebrex b.i.d.
Bextra q.d.
Vioxx q.d.

5 - 17 Non-sedating Antihistamines

The DUR Board has restricted access to non-sedating antihistamines. The OTC formulations for loratadine and loratadine-D (brand are open without a prior approval for 30 cumulative doses per any 30 day period effective July 1, 2003.

Cetirizine Hcl (Zyrtec), fexofenadine Hcl (Allegra), desloratidine (Clarinex) and/or new non-sedating antihistamine formulations require a prior approval. Criteria for prior approval for these legend drugs includes: FAXed copy from patient charts documenting failure on loratidine due to specified adverse drug reaction or failure of efficacy while patient is on loratidine.

5 - 18 Actiq & Long Acting Narcotics

Therapeutic duplication of long acting formulations is not allowed.

Actiq (fentanyl citrate) lozenge is covered only for diagnoses of malignant neoplasms, carcinoma in situ, or neoplasms of unspecified nature. Physicians must enter in correct ICD.9 code on prescription and pharmacist in-turn must enter that code into the diagnoses field. Cumulative limit of 120 units per any 30 days is maximum amount covered. Any use outside of these diagnoses will require a successful petition to the DUR Board.

For purposes of this policy, guideline for maximum daily dose : morphine sulfate 150mg = Duragesic 75mcg = OxyContin 100mg = methadone 50mg

For diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature, prescriber must write correct IDC.9 on prescription and pharmacists in-turn must enter that code into the diagnoses field. Otherwise large quantities will deny. Select other terminal end-stage disease states such as end-stage HIV will require a written PA.

Morphine sulfate long acting formulations:

Chronic non-maliganant pain; has a daily maximum limit of 150mg or 90 capsules/tablets per any 30 day;

Diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature, end stage AIDS, and Pagent's Disease; prescriber must write correct IDC.9 code for Diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature. Select other terminal end-stage disease states such as end-stage HIV will require a written PA.

Duragesic :

Chronic non-maliganant pain; has a maximum limit of 75 mcg or a limit of 15 patches per any 30 day period.

Diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature, end stage AIDS, and Pagent's Disease; prescriber must write correct IDC.9 code for Diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature. Select other terminal end-stage disease states such as end-stage HIV will require a written PA.

Oxycontin :

Chronic non-maliganant pain; has a daily maximum limit of 100mg or a 90 capsules/tablets per any 30 days.

Diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature, end stage AIDS, and Pagent's Disease; prescriber must write correct IDC.9 code for Diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature. Select other terminal end-stage disease states such as end-stage HIV will require a written PA.

Methadone:

Chronic non-maliganant pain; has a daily maximum limit of 50mg or,150 10mg capsules for any 30 days.

Diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature, end stage AIDS, and Pagent's Disease; prescriber must write correct IDC.9 code for Diagnoses of malignant neoplasms , carcinoma in situ, or neoplasms of unspecified nature. Select other terminal end-stage disease states such as end-stage HIV will require a written PA.

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6 REIMBURSEMENT POLICIES

6 - 1 Point-of-Sale System

Effective April 1, 2000, Medicaid requires all pharmacy claims to be submitted electronically through the Point of Sale system. Medicaid will only accept a claim submitted on paper when (1) a client becomes eligible for Medicaid after receiving services (retroactive Medicaid) AND (2) the provider's software cannot support a claim with a previous date of service.

Beginning April 1, 2000, Medicaid will return all Universal Pharmacy Claims (NCPDP) submitted on a paper form to the provider with a cover letter requiring the claim be submitted electronically.

Point of Sale System

The Point of Sale (POS) system provides pharmacists with the capability to submit pharmacy claims electronically. It enables pharmacies to immediately determine Medicaid client eligibility, verify drug coverage, and have "real time" claim processing. Federal law has mandated the use of NCPDP 5.1 effective October 17, 2003. NCPDP5.1 is the national claim format developed by the National Council for prescription drugs. All pharmacies routinely billing Utah Medicaid must use NCPDP 5.1 when billing Medicaid through Point-of-Sale.

Pharmacy claims are routed electronically through network companies (switches). The network companies currently participating in this process are National Data Corporation (NDC) and Envoy Corporation. Other interested and qualified networks may also participate.

For information about submitting claims through NDC or Envoy Corporation, please call NDC Easy claim Customer Support at 1-800-388-2316 or Envoy at 1-800-333-6869.

Included with this manual are instructions, and an Resolution List to assist in resolving denials.

6 - 2 Prospective Drug Utilization Review (PRODUR)

PRODUR, Prospective Drug Utilization Review Program, is an adjunct to the Point Of Sale (POS) system used for pharmacy claims. It is a system to monitor the client's complete Medicaid drug history, including any pharmacy or physician. It identifies on the computer screen, as the prescription is being filled, any potential adverse drug events (ADE) of severity level 1, drug duplicates as well as therapeutic class drug duplicates. PRODUR contains modules to review drug interactions and responds with a message to the pharmacist. Modules include: Minimum - Maximum Dose, Dose range (cumulative dose), Duplication, Drug - Drug Interaction, Drug - Disease Interaction, Minimum/Maximum Pediatric Daily Dose, Minimum/Maximum Geriatric Daily Dose and Side Effects Module. (Criteria for the Side Effects Module are listed in this chapter)

If you would like more information on PRODUR, please contact Medicaid Information.

Criteria for Side Effects Module

For the Side Effects Module, First DataBank© has established the following editorial criteria:

a. **Frequency:** A side effect is defined as 'common or more frequent' when the incidence is greater than or equal to 10%. A side effect is defined as 'rare or less frequent' when the incidence is less than 10%.

b. **Severity:** A side effect is defined as 'less severe' if it is nonthreatening (e.g., constipation). A side effect is defined as 'severe' if it may be life-threatening (e.g., agranulocytosis).

c. **Visibility:** A side effect id defined as 'visible' if it is definitely detectable (e.g., rash). This includes detection by the patient or by someone other than the patient. A side effect is defined as 'may be visible' if the delectability is less clear cut. For example, a headache is not exactly visible, per se. However, the patient may be able to convey that he has a headache. In these cases, it is assumed that the patient is responsive or communicative. Also, assessment is based on a physical examination which may include use of a blood pressure cuff, thermometer, stethoscope, weight measurement, and fluid input/output measurement. Finally, a side effect is defined as ' not visible' if it is definitely not visible (e.g., neutropenia), or if it is not detectable by routine physical exam.

d. **Lab tests:** The intent of this indicator is not to establish which lab tests should be ordered for a given drug as baseline or for monitoring. Rather, it is intended to indicate whether or not lab tests are necessary as follow-up for a given drug/side effect pair.

e. **Physician:** The physician should always be contacted regarding severe side effects. In addition, the physician should be contacted whenever lab tests are required.

6 - 3 Maximums and Minimums

Utah Medicaid has implemented the Maximums and Minimums fields with acceptable quantities. Drugs available in certain quantities are covered in that quantity and multiples of those quantities. For example, an injectable product only available as a 2.5 ml. vial will have a minimum of 2.5 and a maximum of a multiple of 2.5. Products such as antibiotics in 75 ml, 100 ml, 150 ml., or 200 ml are covered only in those quantity and multiples of those quantities. Other quantities, such as 35 ml for a 75 ml product, or 430 for the product, are not covered.

6 - 4 Decimal Quantities

Starting July 1, 1998, pharmacies must bill using metric decimal quantities to the second decimal when entering the units dispensed. Use metric decimal quantity field (Field 442-E7). This change affects ophthalmic preparations, otic preparations, inhalers and selected injectable preparations. For example: Vanceril® inhaler (NDC 00085073604) must be expressed as 16.80 units or an even multiple of 16.80 units. (Examples: 2 x 6.80 = 33.60 units; 3 x 16.80 = 50.40 units).

As of July 1, 1998, you may no longer round up the decimal quantity to the next whole number. If the decimal quantity is rounded up to the next whole number, the claim will be rejected.
When the Point of Sale program began in 1994, each pharmacy that signed on agreed to accept Version 3.2 of NCPDP's standardized electronic claims format. As of July 1, the standard will change to require decimal quantities to the second decimal.

6 - 5 Counseling

Effective use of the Point-of-Sale and PRODUR systems is the basis for patient counseling.

Patient counseling is mandated by OBRA 1990, OBRA 1993, and Utah Pharmacy Practice Act. Counseling the client and interfacing with the physician are integral parts of the pharmacy function of dispensing. Audits of pharmacies are performed regularly in conjunction with the Department of Professional Licensing (DOPL).

Counseling is included as part of the dispensing fee, and the pharmacist must instigate dialog by offering to counsel the client. Mail order pharmacies which do not offer counseling up-front are subject to a lesser fee. Providing the package insert is not considered counseling.

6 - 6 Rebate Program

OBRA 1990 mandates that all drug manufacturers whose products were dispensed to Medicaid clients provide a discount or rebate back to the individual states. Medicaid is the single largest user of drugs nationwide and, as such, is entitled to a discount such as hospitals and other organizations receive.

Each quarter of a calendar year, Medicaid produces a list of drugs by National Drug Code (NDC). The list includes the number of units of each NDC which the state has paid to all pharmacies. The list is sent to each manufacturer. The manufacturer applies its rebate criteria, multiplies the number of units by the rebate per unit (RPU) and pays Medicaid that rebate amount.

To ensure accuracy in the drug list, pharmacies shall ensure claims submitted conform with the following reporting requirements:

1. All products must be billed with correct decimals for any fractions dispensed. Here are some examples of correct decimals for fractional quantities: 2.5ml; 15 gram tubes; 12.5 for 1/8 oz. ointments; 15.7ml inhalers.

2. All medications must be billed in accurate quantities, particularly injectable medications. Liquid vials should be billed by ml. For example, a 10 ml. vial equals 10 units, a 20 ml. vial equals 20 units. Dry powder vials are billed as 'each'. Each vial equals quantity one. The diluent used to liquefy a dry powder is billed separately by NDC and units (ml.) of liquid.

   Some items are limited by computer edits to allow only a specified minimum or an even multiple of that minimum, i.e. 3 x 2.5ml.

3. Ensure that your computer entries for quantities are accurate.

   Pharmacies shall make sure that computer 'stutter' does not result in inaccurate quantities, such as 60,000 instead of 60.

4. Only the NDC of the product dispensed is billed. The NDC for the generic brand is billed when a generic brand is dispensed. Do NOT bill Medicaid for a name brand NDC when a generic brand was dispensed. Common billing errors include billing for Darvocet N, Keflex, Mellaril, Stelazine, or Depakene when generics were dispensed.

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5. The pharmacist or technician shall write the name of the manufacturer on the prescription when actually transferring a product from a stock container into a vial for a specific patient. To ensure accuracy, Medicaid requires the name of the manufacturer to be written on the prescription by the pharmacist or technician who is actually holding the product dispensed. A manufacturer is permitted under OBRA 90 to request verification of the NDC billed to Medicaid or requesting invoices to substantiate purchases.

   Manufacturers gather data such as names, addresses, reimbursement and specific errors made by pharmacies when dispensing. Manufacturers assume it is not likely that pharmacies repeatedly accept generic reimbursement while billing innovator NDCs. Therefore, when a manufacturer denies the rebate and names pharmacies which billed for name brand NDCs but accepted generic level reimbursement, both the manufacturer and Medicaid will request a copy of the prescription to verify the manufacturer written on the prescription and a copy of the pharmacy purchase invoice. Suitable penalties will be applied when discrepancies exist between the manufacturer identified and the NDC billed.

7 NON-COVERED DRUGS AND SERVICES

Only drugs and services described previously as covered are reimbursable by Medicaid. This chapter summarizes those products and services which are not covered.

A. Any drug without a prescription, including over-the-counter drugs, is not a benefit.

B. Any drug or product for which an NDC number is not available is not a Medicaid benefit. [Social Security Act, Section 1927 (K)(3)]

C. Over-the-counter drugs not on the approved Over-the-counter Drug list are not a Medicaid benefit.

D. Certain OTC drugs on the approved list are not a benefit for a Medicaid client who is a resident of a nursing home. When this restriction on a drug is indicated, all dosage forms apply.

E. Early refills of prescriptions are not a Medicaid benefit except as specified in Chapter 4 - 7, Early Refills.

F. Drug classes not covered as allowed by OBRA and Utah Law are not a Medicaid benefit.

G. Off-Label Drug Use is not a Medicaid benefit.

Only uses approved as described in Chapter 2 - 5, Formulary, item B, are covered by Medicaid.

H. Less-Than-Effective (DESI) Drugs are not a Medicaid benefit.

As stated in Chapter 5 - 4, Desi Drugs, drugs are classified into five groups. Drugs in groups 4, 5, and 6 are NOT covered by Medicaid. DESI drugs are combinations of products and single products that, in the Federal Drug Efficacy Study Information (DESI), have not been proven to the federal Health Care Financing Administration (HCFA) to be effective for the conditions indicated in the information packet.

I. Drugs given by a hospital to a patient at discharge (take-home drugs) are not a Medicaid benefit.

J. Breast milk substitutes are not a Medicaid benefit.

K. Multiple vitamins (except for prenatal vitamins with 1 mg. folic acid for pregnant women, and multiple vitamins with Fluoride for children through age 5) are not a Medicaid benefit.

L. Baby food is not a Medicaid benefit.

M. New pharmaceutical products on the market are often covered by the Medicaid Physician Program and not covered by the Pharmacy Program. The following products are examples: Synagis, Remicade, Zemplar, TRELSTAR®.

Also, some products removed from coverage by the Pharmacy Program continue to be available through the Physician Program. For example, effective April 1, 2002, epoeitin alpha (Epogen, Procrit) will only be available through the Physician Program.

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